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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,570	09/09/2003	Martin Morrissey	MCA-616 US	5746
25182	7590	06/20/2007		
MILLIPORE CORPORATION 290 CONCORD ROAD BILLERICA, MA 01821			EXAMINER MCKANE, ELIZABETH L	
			ART UNIT 1744	PAPER NUMBER
			MAIL DATE 06/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,570

Applicant(s)

MORRISSEY ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12 and 14-16 is/are rejected.
- 7) ☒ Claim(s) 7, 13 and 17-20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12222003, 06182004, 06212004</u> | 6) <input type="checkbox"/> Other: ____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-6, 8-12, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Padgett (US 4,644,586).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38** adjacent the interface between the first and second portions to create a sealed, sterile portion. See col.4, lines 10-38; Figures 4-6.

With respect to claim 3 and the limitation wherein “the bag contains components to be sterilized and transferred to an isolator,” this limitation is considered to be an intended use of the bag and does not structurally limit the bag itself.

As to claims 5 and 6 and the limitations wherein “the bag and its contents being under a slight vacuum” and “the bag and its contents being under a slight positive pressure” are not considered to be structurally limiting on the bag but are intended uses of the bag.

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3. Claims 1, 3-6, 8, 12, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Trewella et al. (US 3,073,507).

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15. The intended use of the device does not structurally limit the bag in any patentable sense.

With respect to claim 3 and the limitation wherein “the bag contains components to be sterilized and transferred to an isolator,” this limitation is considered to be an intended use of the bag and does not structurally limit the bag itself.

As to claims 5 and 6 and the limitations wherein “the bag and its contents being under a slight vacuum” and “the bag and its contents being under a slight positive pressure” are not considered to be structurally limiting on the bag but are intended uses of the bag.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trewella et al. in view of McDonald (US 6,030,578).

Trewella et al. is silent with respect to a closed collar or port attached to the non-porous section. McDonald, however, discloses a container **201** for sterilizing and transferring articles to a sterile enclosure. The container includes a collar **202** for attachment to a sterile enclosure during transferring of the sterilized articles. This collar is certainly capable of use as a pressure or vacuum port, as well. Since the bag of Trewella et al. is disclosed for use in the sterilization of medical articles, it would have been obvious to use the bag of Trewella et al. in the sterile

environment of McDonald and when doing so, to provide a collar for connection to the enclosure.

Allowable Subject Matter

8. Claims 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: With respect to claims 17 and 18, the prior art of record fails to teach or suggest either applying a vacuum or positive pressure to the second section during or after the formation of the second seal. For example, Padgett is silent with respect to any means for applying a vacuum or pressure. Trewalla et al. teaches that while both positive pressure and vacuum are employed during sterilization, the pressure within the bag is brought back to atmospheric at the end of sterilization. See col.1, lines 47-62. It is at this point that the bag is sealed. Thus, no vacuum or pressure is applied during or after the formation of the second seal. Lastly, McDonald specifically teaches sterile docking at ambient pressures (col.3, line 66 to col.4, line 4). As to claims 19 and 20, none of the prior art of record teaches or suggests a need to apply an integrity test to the bag after formation of the second seal.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ivanov et al. (US 5,868,244) teaches packages having a porous and a non-porous


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section, wherein after sterilization the non-porous sections of the packages are sealed off from the porous section.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leigh McKane
Primary Examiner
Art Unit 1744

elm
17 June 2007